MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

INSTRUCTIONS

FOR COMPLETING THE MEDWATCH FORM

(For **VOLUNTARY** reporting of adverse events and product problems)

General Instructions:

- Please type or use black ink.
- Complete all sections that apply to your report.
- To complete an item when information is not available, use:
  - **NA** for not applicable
  - **NI** for no information at this time (but may be available at a later date)
  - **UNK** for unknown
- Dates should be entered as month/day/year (e.g., June 3, 1993 = 06/03/93). If exact dates are unknown, make your best guess.
- For narrative entries, if the fields do not provide adequate space, attach an additional page(s), and indicate the appropriate section and block number next to the narrative continuation.
- If reporting more than two (2) suspect medications or one (1) suspect medical device, use another copy of the form with only section C or section D filled in as appropriate.
- All attached pages should be identified as page ___ of ___.
- Section C “Suspect Medication(s)” may be used to report on special nutritional products as well as drugs or biologics.
- Call 1-800-FDA-1088 to obtain copies of the form.
- Adverse events with vaccines should not be reported on this form. Call 1-800--822-7967 for a copy of the VAERS form.

Section A: **Patient information -** Please complete a separate form for each patient. In a case where the report is on a medical device and multiple patients were adversely affected through the use of the same device, please indicate the number of patients in B5 (event description) and complete A1 - A3 for one patient.

A1: **Patient identifier** - Please provide the patient's initials or some type of identifier that will allow you, the reporter, to locate the case if you are contacted for followup. Do NOT use the patient's name or social security number.

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law.

A2: **Age** - Enter the patient's birthdate, if known, or the patient's age at the time of event onset.

- if the patient is **3 years or older,** use **years** (e.g., 4 years).
- if the patient is **less than 3 years old,** use **months** (e.g., 24 months).
- if the patient is **less than 1 month old,** use **days** (e.g., 5 days).

Make your best estimate if exact age is unknown.

If the adverse event is a congenital anomaly, use the age or birthdate of the child or the date pregnancy is terminated. If information is available as to time during pregnancy when exposure occurred, please indicate that in narrative section B5.

A3: **Sex** - If the adverse event is a congenital anomaly, report the sex of the child.

A4: **Weight** - Please indicate whether the weight is in pounds (lbs) or kilograms (kgs). Make your best estimate if exact weight is unknown. If the adverse event is a congenital anomaly, use the weight of the child at birth.

A. Patient information			
1. **Patient identifier** In confidence	2. **Age at time of event:** or _____ **Date of birth:**	3. **Sex** ☐ female ☐ male	4. **Weight** _____ lbs or _____ kgs

Section B: **Adverse event or product problem -**

B1: **Adverse event and/or product problem** - Choose the appropriate box. Both boxes should be checked if a product problem may have contributed to the adverse event.

Adverse event: any incident where you suspect that the use of a medication (drug or biologic) at any dose, a medical device (including in-vitro diagnostics) or a special nutritional product (e.g., dietary supplement, infant formula or medical food) may have resulted in an adverse outcome in a patient.

It is not necessary to be certain of a cause/effect relationship. Suspicion of an association is sufficient reason to report. Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Please limit your submissions to those events that are SERIOUS. An event is classified as **SERIOUS** when the patient outcome is:

- death
- life-threatening (at substantial risk of dying at the time of the event)
- disability (significant, persistent or permanent)
- hospitalization - initial or prolonged
- congenital anomaly
- required medical or surgical intervention to prevent permanent impairment or damage

Of course, you may send in your report even if your case does not meet any of these specific criteria and you feel strongly that FDA should review the report. In that case, you should choose the "other" category in B2 and specify the reason for reporting. The actual narrative describing the event should be entered in block B5.

Product problem (e.g., defects/malfunctions): any concern regarding the quality, performance or safety of any medication, medical device, or special nutritional product. Problems include concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling
- suspected super potent or subpotent medication
- device malfunction

Note: You may also report product problems (not adverse events) directly to FDA, 24 hours a day by dialing 1-800-FDA-1088.

B2: **Outcomes attributed to adverse event -**

Death - Only check if you suspect that the death was an OUTCOME of the adverse event. Include the date if known. (DO NOT check if the patient happened to die while using a medical product but there was no suspected association between the event and the use of the product).

Life-threatening - Check if you suspect the patient was at substantial risk of dying at the time of the adverse event or if you think that use or continued use of the product might have resulted in the death of the patient.

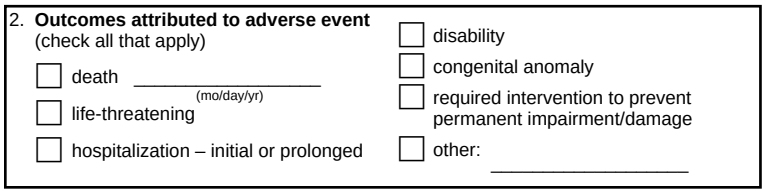
Hospitalization (initial or prolonged) - Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event (e.g., do NOT check hospitalization if a patient in the hospital receives a medical product and subsequently develops an otherwise nonserious adverse event, unless the adverse event prolongs the hospital stay.)

Disability - Check if the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.

Congenital anomaly - Check if you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

Required intervention to prevent permanent impairment or damage - Check if you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function or to prevent permanent damage to a body structure that you suspect was due to the use of a medical product.

Other - Check only if the other categories are not applicable to your report. Briefly describe the patient outcome that led you to submit this report. The actual narrative of the event should be entered in block B5.



B3: **Date of the event** - Provide your best estimate of the date of first onset of the adverse event. For congenital anomalies, the date of birth or the date pregnancy is terminated should be used.

If the day is unknown, month and year are acceptable.

If day and month are unknown, year is acceptable.

B4: **Date of this report** - today's date.

3. **Date of event** (mo/day/yr)	4. **Date of this report** (mo/day/yr)

B5: **Describe event or problem** - For an **adverse event:** Describe the event in detail including a description of what happened and a summary of all relevant clinical information (medical status prior to the event, signs, symptoms, diagnoses, clinical course, treatment, outcome, etc.) If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by your institution) you may attach copies of these records with any confidential information deleted. ***Please do not identify any patient, physician or institution by name. The reporter's identity should be provided in full in Section E.***

Results of relevant tests and laboratory data should be entered in block B6. Preexisting medical conditions and other relevant history belong in block B7.

For a **product problem:** Describe the problem in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. If available, the results of any evaluation of a malfunctioning device and if known any relevant maintenance/ service information should be included in this section. For a medication or special nutritional product quality problem please indicate if you have retained a sample that would be available to FDA.

5. **Describe event or problem**

B6: **Relevant tests/laboratory data, including dates** - Include any relevant baseline laboratory data prior to the administration or use of the medical product, all laboratory data used in diagnosing the event and any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event. Include any available pre- and post-event medication levels and dates if applicable). Include a synopsis of any relevant autopsy, pathology, engineering or lab reports, if available. If preferred, copies of any reports may be submitted as attachments with all confidential information deleted. ***Please do not identify any patient, physician or institution by name. The reporter's identity should be provided in full in Section E.***

6. **Relevant tests/laboratory data,** including dates

B7: **Other relevant history, including preexisting medical conditions** - Knowledge of other risk factors can help when evaluating a reported adverse event. If available, please provide information on other known conditions in the patient (e.g., hypertension, diabetes, renal/hepatic dysfunction, etc.) and significant history (allergies, race or ethnic origin, pregnancy, smoking and alcohol use, drug abuse, etc.)

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Section C: **Suspect medication(s)** - For adverse event reporting - a **suspect** medication is one that you suspect is associated with the adverse event. In block C10 enter other **concomitant** medical products (drug, biologic, device, etc.) that a patient was using at the time of the event but you don't think were involved in the event. Up to two (2) **suspect** medications may be reported on one form (#1 = first suspect product, #2 = second suspect product). Attach an additional form if you wish to report more than two suspect medications for one adverse event.

For product problem reporting - a **suspect** medication is the product that is the subject of the report. A separate form should be filed for each individual product problem report. Identification of pharmaceutical manufacturer and labeled strength of the product is important for prescription or non-prescription products.

This section may also be used to report on special nutritional products (e.g., dietary supplements, infant formula or medical foods) or other product regulated by FDA.

C1: **Name** - Use the trade name as marketed. If unknown or if no trade name, use the generic name (with the manufacturer/labeler's name, if known). For quality problem reports include the manufacturer's name and the labeled strength for both prescription and non-prescription products.

C. Suspect medication(s)
1. **Name** (give labeled strength & mfr/labeler, if known) #1 #2

C2: **Dose, frequency & route** - Describe how the product was prescribed to be administered to or used by the patient (e.g., 500mg, QID orally, or 10mg every other day IV).

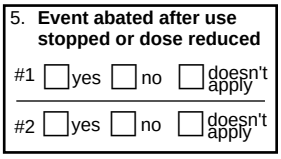
C3: **Therapy dates** - Provide the date administration was started (or best estimate) and the date stopped (or best estimate). If no dates are known, an estimated duration is acceptable (e.g., 2 years) or if therapy was less than one day, then duration is appropriate (e.g., 1 dose or 1 hour for an IV).

2. **Dose, frequency & route used**	3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
#1	#1
#2	#2

C4: **Diagnosis for use** - Provide the indication for which the product was prescribed or used in treating this particular patient.

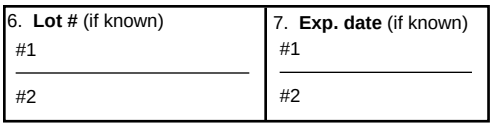
4. **Diagnosis for use** (indication)
#1
#2

C5: **Event abated after use stopped or dose reduced -** If available, this information is particularly useful when evaluating a suspected adverse event. Please provide supporting lab tests and dates, if available, in B6.

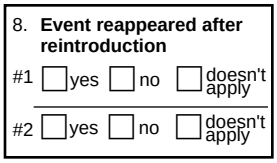


C6: **Lot #** - If known, please include the lot number(s) with all product problem reports or any adverse event report with a biologic, or any therapeutic lack of effect with a medication.

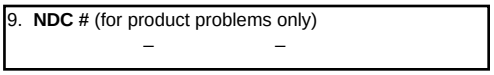
C7: **Expiration date** - Please include with all product problem reports.



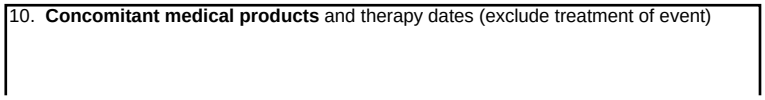
C8: **Event reappeared after reintroduction -** If applicable, this information is particularly useful in evaluating a suspected adverse event. Please provide supporting lab tests and dates, if available, in B6.



C9: **NDC #** - The national drug code number is only requested when reporting a drug product problem. It can be found on the product label and/or packaging. Zeros and dashes should be included as they appear on the label.



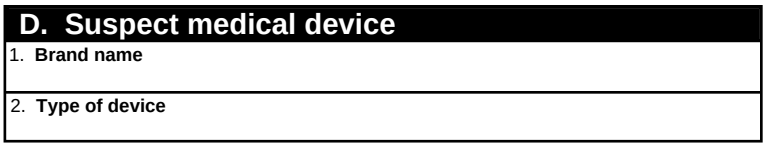
C10: **Concomitant medical products and therapy dates -** Information on the use of concomitant medical products can frequently provide insight into previously unknown interactions between products or provide an alternate explanation for the observed adverse event. Please list and provide therapy dates for any other medical products that a patient was using around the time of the event. Do not include products used to treat the event.



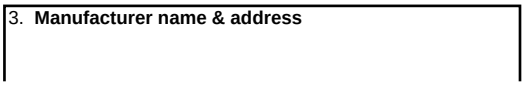
Section D: **Suspect medical device** - For adverse event reporting - a **suspect** medical device is one that you suspect is associated with the adverse event. In D10 you will be asked to report other **concomitant** medical products that a patient was using at the time of the event but you don't think were involved in the event. Attach an additional form if you wish to report more than one suspect medical device for one adverse event.

D1: **Brand name** - The trade or proprietary name of the suspect product as used in product labeling or in the catalog. (e.g., Easyflo Catheter, Reliable Heart Pacemaker, etc.). This information may be on a label attached to a durable device, may be on a package of a disposable device, or may appear in labeling materials of an implantable device.

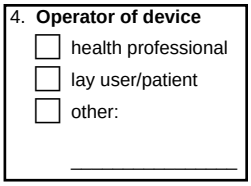
D2: **Type of device** - The generic or common name of the suspect product or a generally descriptive name (e.g., Foley catheter, heart pacemaker, patient restraint, etc.).



D3: **Manufacturer name & address** - If available, list the full name and mailing address of the manufacturer of the product.



D4: **Operator of device** - Please indicate the type (not the name) of person operating or using the device on the patient at the time of the event.
Health professional = physician, nurse, respiratory therapist, etc.
Lay user/patient = person being treated, parent/spouse/friend of the patient
Other = nurses aide, orderly, etc.



D5: **Expiration date** – If available, this date can often be found on the device itself or printed on the accompanying packaging.

D6: **Product identification numbers** - If available, please provide any or all identification numbers associated with the suspect device exactly as they appear on the device or labels. These numbers can be found on the device itself and/or in the accompanying literature and packaging. If the type of number is unknown, list on the other # line.

Model # - the exact model number found on the device label or accompanying packaging, including any revision level information.

Catalog # - the number as it appears in the manufacturer's catalog.

Serial # - can be found on the device label. This number, assigned by the manufacturer should be specific to each device.

Lot # - can be found on the label or packaging material.

Other # - any other applicable identification number (e.g., component number, product number, batch number, part number, etc.).

6.
model # _____

catalog # _____

serial # _____

lot # _____

other #

D7: **If implanted, give date** - For medical devices that are implanted in the patient, please provide the date (or your best estimate). If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D8: **If explanted, give date** - If an implanted device was removed from the patient, please provide the date (or your best estimate). If day is unknown, month and year is acceptable. If month and day are unknown, year is acceptable.

7. **If implanted, give date** (mo/day/yr)

8. **If explanted, give date** (mo/day/yr)

D9: **Device available for evaluation?** - To evaluate a reported problem with a medical device it is often critical for the manufacturer to be able to examine the suspect product. Please indicate whether the device is available for evaluation. If it is not, indicate whether you returned the product to the manufacturer and if so the date of the return. (Do not send the device to the FDA).

9. **Device available for evaluation?** (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on _____ (mo/day/yr)

D10: **Concomitant medical products and therapy dates** - Information on the use of concomitant medical products can frequently provide insight into previously unknown interactions between products or provide an alternate explanation for the observed adverse event. Please list and provide therapy dates for any other medical products that a patient was using at the time of the event. Do not include products used to treat the event.

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

Section E: **Reporter** - FDA recognizes that confidentiality is an important concern to health care professionals in the context of adverse event reporting. The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. However, to allow for timely followup in serious cases, the reporter's identity may be shared with the manufacturer unless requested otherwise in E5. The FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

E1: **Name, address & phone #** - Please provide the name, mailing address and phone number of the person who can be contacted to provide information on the event if followup is necessary. This person will also receive an acknowledgment letter from the MEDWATCH program. This information is necessary for both adverse event and product problem reports.

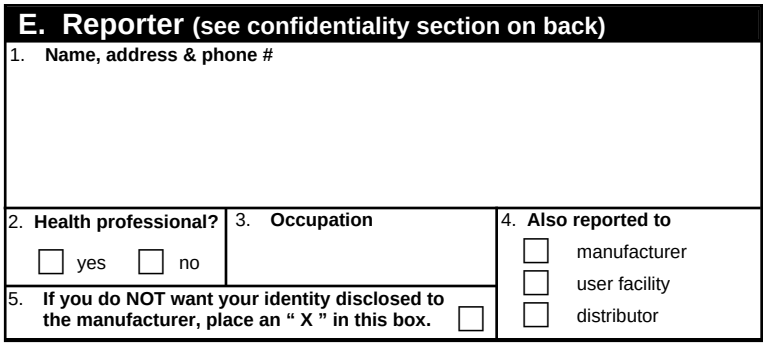
E2: **Health professional?** - Please indicate whether you are a health professional (e.g., physician, pharmacist, nurse, etc.) or not.

E3: **Occupation** - Please indicate the type of health professional or reporter occupation, and indicate specialty if appropriate.

E4: **Also reported to** - Please indicate whether you have also notified or submitted a copy of this report to the manufacturer of the product, the distributor of the product, and/or, for medical device reports only, the user-facility (institution) in which the event occurred. This information helps to track duplicate reports in the Agency data base.

E5: **Release of reporter's identity to the manufacturer** - In the case of a serious adverse event, the Agency may provide name, address and phone number of the reporter in E1 to the manufacturer of the suspect product.

If you do NOT want your identity released to the manufacturer please put an X in the box.



Your participation in MEDWATCH is invaluable. This form (3500) is designed for voluntary reporting of adverse events and product problems with medications, medical devices, special nutritional products and other products regulated by FDA.

The MEDWATCH program would appreciate any comments you have about your experience in using the form. Please mail them to:

MEDWATCH: The FDA Medical Products Reporting Program
Office of the Commissioner HF-2
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

or call (301) 443-0117